



Mitchell E. Daniels, Jr.  
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.  
State Health Commissioner

**DATE:** December 16, 2010

**TO:** All Local Health Departments  
Attn: Chief Food Inspection Officer

**FROM:** A. Scott Gilliam, MBA, CP-FS  
*ASG*  
Director, Food Protection Program

**SUBJECT:** McNeil Consumer Healthcare Recall

**SUGGESTED**

**ACTION:** Unclassified Recall; All lots of ROLAIDS® Extra Strength Softchews, ROLAIDS® Extra Strength plus Gas Softchews, and ROLAIDS® Multi-Symptom plus Anti-Gas Softchews (full product details below) distributed in the United States due to foreign materials in the products, including metal and wood particles; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the products being recalled may be distributed in the State of Indiana. The recalled products are sold in retail stores nationwide. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.

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**Recall -- Firm Press Release**

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

**McNeil Consumer Healthcare Announces Voluntary Recall Of All Lots Of Rolaid® Extra Strength Softchews, Roldaid® Extra Strength Plus Gas Softchews, And Roldaid® Multi-Symptom Plus Anti-Gas Softchews Sold In The United States**

**Contact:**

McNeil Consumer Healthcare  
<http://www.rolaids.com><sup>9</sup>  
1-888-222-6036

**FOR IMMEDIATE RELEASE** - December 9, 2010 - McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc. is voluntarily recalling all lots of ROLAIDS® Extra Strength Softchews, ROLAIDS® Extra Strength plus Gas Softchews, and ROLAIDS® Multi-Symptom plus Anti-Gas Softchews (full product details below) distributed in the United States. McNeil is taking this action following some consumer reports of foreign materials in the product, including metal and wood particles. The company's investigation has determined that the materials were potentially introduced into the product during the manufacturing process at a third party manufacturer. While the risk of serious adverse health consequences is remote, McNeil Consumer Healthcare advises consumers who have purchased these recalled products to discontinue use.

While our investigation is ongoing we have suspended production of ROLAIDS® Extra Strength Softchews, ROLAIDS® Extra Strength plus Gas Softchews, and ROLAIDS® Multi-Symptom plus Anti-Gas Softchews and will not restart production until corrective actions have been implemented.

Consumers who purchased product included in this recall should contact McNeil Consumer Healthcare, either at <http://www.rolaids.com><sup>10</sup> or by calling 1-888-222-6036 (Monday-Friday 8 a.m. to 8 p.m. Eastern Time, and Saturday-Sunday 9 a.m. to 5 p.m. Eastern Time) for instructions about receiving a refund. Consumers who have medical concerns or questions should contact their healthcare provider.

Any adverse reactions may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: <http://www.fda.gov/MedWatch/report.htm><sup>11</sup>
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: <http://www.fda.gov/MedWatch/getforms.htm><sup>12</sup>. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).

Product Information: Product NDC numbers can be located on the label of the package above the brand name. Lot Numbers and Expiration Dates can be found on back, side or bottom label of the package. If you cannot find the NDC number, lot number, or expiration date on the label, [Click here](#)<sup>13</sup> for examples or call the Consumer Care Center at 1-888-222-6036.

[CLICK HERE](#)<sup>14</sup> TO FIND OUT IF YOUR ROLAIDS® SOFTCHEWS PRODUCT IS PART OF THE DECEMBER 9, 2010 RECALL.

FULL RECALLED PRODUCT LIST:

| Product Name  | Lot Number  | UPC          |
|---|---|--------------|
| <b>ROLAIDS® Extra Strength Softchews, Wild Cherry</b>                         |   |              |
| ROLAIDS® Extra Strength Softchews, Wild Cherry, 6 count                       | 9015A, 9016A, 9019A, 9140A, 9138A, 9210A, 9211A, 9315A, 9316A   | 312547655200 |
| ROLAIDS® Extra Strength Softchews, Wild Cherry, 18 count (3 packs of 6 count) | 9075A, 9076A, 9103A, 9098A, 9104A, 9239A, 9240A, 9348A  | 312547655255 |
| ROLAIDS® Extra Strength Softchews, Wild Cherry, 42 count (7 packs of 6 count) | 9065A, 9068A, 9069A, 9131A, 9132A, 9208A, 9209A, 9286A, 9287A   | 312547655316 |
| <b>ROLAIDS® Extra Strength Softchews, Cherry</b>                              |   |              |
| ROLAIDS® Extra Strength Softchews, Cherry, 6 count                            | 0109A, 0114A, 0115A, 0134A, 0135A, 0165A, 0238B, 0239A, 0239C, 0262A, 0264A   | 312547655200 |
| ROLAIDS® Extra Strength Softchews, Cherry, 18 count bag                       | 9349AG2, 9350AG1, 0015AG2, 0015AG3, 0050AG1, 0051AG1, 0053BG2, 0106BG2, 0107AG1, 0108AG1, 0108BG3, 0108CG1, 0129BG1, 0133AG1, 0133AG2, 0165BG2, 0191BG1, 0191CG1, 0191DG1, 0213AG2, 0238AG1, 0238AG2, 0246AG1                                     | 300450649188 |
| ROLAIDS® Extra Strength Softchews, Cherry, 36 count bag                       | 9350AG2, 0012AG1, 0013AG1, 0014AG1, 0015AG1, 0015AG4, 0050AG2, 0053AG2, 0053BG1, 0053BG2, 0094AG1, 0106AG1, 0106BG1, 0108AG2, 0108BG2, 0191AG1, 0139BG2, 0165BG1, 0191BG1, 0207AG1, 0207AG2, 0213AG1, 0227AG1, 0246AG2, 0247AG1, 0265AG1, 0266AG1 | 300450649362 |
| <b>ROLAIDS® Extra Strength plus Gas Softchews, Tropical Fruit</b>             |   |              |
| ROLAIDS® Extra Strength plus Gas Softchews, Tropical Fruit, 6 count           | 9005A, 9006A  | 312547065733 |

|   |   |              |
|---|---|--------------|
| ROLAIDS® Extra Strength plus Gas Softchews, Tropical Fruit, 12 count (2 packs of 6 count) | 9022A, 9027A, 9118A, 9119A, 9195A, 9196A  | 312547065757 |
| ROLAIDS® Extra Strength plus Gas Softchews, Tropical Fruit, 36 count (6 packs of 6 count) | 9166A, 9167A  | 312547065771 |
| <b>ROLAIDS® Multi-Symptom plus Anti-Gas Softchews, Tropical Fruit</b>                     |   |              |
| ROLAIDS® Multi-Symptom plus Anti-Gas Softchews, Tropical Fruit, 6 count                   | 0017B, 0095A, 0096B, 0259A, 0260A   | 300450657060 |
| ROLAIDS® Multi-Symptom plus Anti-Gas Softchews, Tropical Fruit, 12 count bag              | 9351BG1, 9352AG1, 0016AG1, 0059AG2, 0059BG1, 0059BG2, 0060AG2, 0167AG2, 0167AG3, 0203AG1, 0204AG1   | 300450657121 |
| ROLAIDS® Multi-Symptom plus Anti-Gas Softchews, Tropical Fruit, 24 count bag              | 9352AG2, 9352BG2, 0016AG2, 0017AG1, 0057BG1, 0058AG1, 0059AG1, 0059BG3, 0060AG1, 0129AG1, 0132AG1, 0167AG1, 0167BG1, 0204AG2, 0205AG1, 0230AG1, 0231AG1 | 300450657244 |

[CLICK HERE<sup>15</sup>](#) TO FIND OUT IF YOUR ROLAIDS® SOFTCHEWS PRODUCT IS PART OF THE DECEMBER 9, 2010 RECALL.

[CLICK HERE<sup>16</sup>](#) FOR A REFUND OF YOUR PRODUCT

[CLICK HERE<sup>17</sup>](#) TO SEE FREQUENTLY ASKED QUESTIONS

[CLICK HERE<sup>18</sup>](#) FOR INFORMATION ABOUT RECALLS OF ROLAIDS® AND OTHER PRODUCTS